

Amendment After Allowance Under 37 C.F.R. § 1.312

Applicant: Northrup III et al.

Serial No.: 09/800,613

Filed: March 7, 2001

Docket No.: M104.120.102

Title: DEVICE FOR CREATING AN ANASTOMOSIS, INCLUDING PENETRATION STRUCTURE AND
EVERSION STRUCTURE

Amendments to the Claims:

This listing of claims replaces all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Previously Presented) A surgical staple for use in creating an everted anastomosis of at least two anatomical structures, the staple comprising a staple body constructed for bending and at least two everting elements connected to the staple body, the everting elements protruding from the staple body, the staple body and the everting elements being constructed and arranged so that when the staple body is bent around cut ends of the anatomical structures, the everting elements contact the anatomical structures at everting-element contact locations, the everting elements are in an apposed relationship, and the inner layers of the anatomical structures are held together between the everting elements to form the everted anastomosis; the staple further comprising at least two spacing elements connected to the staple body, the spacing elements being constructed and arranged so that when the staple body is bent around the cut ends of the anatomical structures, the spacing elements contact the anatomical structures at spacing-element contact locations, the spacing elements are in an ~~apposing~~ apposed relationship, and the cut ends of the anatomical structures are held together between the spacing elements; wherein the spacing-element contact locations are closer to each other than the everting-element contact locations are to each other when the staple body is bent, such that the ~~apposing~~ apposed everting elements are generally prevented from crushing the anatomical structures.

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2. (Cancelled)

3. (Cancelled)

4. (Cancelled)

5. (Previously Presented) The staple of claim 1, wherein the apposed spacing elements define an inner radius of the bent staple and the apposed everting elements define an outer radius of the bent staple, the radii being taken from the bend in the staple, the inner radius being smaller than the outer radius.

6. (Cancelled)

7. (Cancelled)

8. (Previously Presented) The staple of claim 1, wherein one of the spacing elements is disposed along the staple body and the other of the spacing elements is disposed adjacent the staple body.

9. (Previously Presented) The staple of claim 1, wherein the spacing elements are disposed closer to the middle of the staple than the everting elements.

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10. (Original) The staple of claim 1, wherein the everting elements are disposed at the very ends of the staple body.

11. (Previously Presented) The staple of claim 1, further comprising a penetrating element constructed to penetrate all of the at least two anatomical structures when the everting elements are in the apposed relationship.

12. (Previously Presented) The staple of claim 11, wherein the penetrating element is disposed at only one end of the staple body.

13. (Previously Presented) The staple of claim 1, wherein one of the everting elements forms a general T-shape with respect to the staple body at one end of the staple; further wherein one other of the everting elements forms a general L-shape with respect to the staple body at another end of the staple.

14. (Previously Presented) The staple of claim 1, wherein the end of one of the everting elements is aligned with the staple body; further wherein one other of the everting elements is centered on the staple body; such that the staple is asymmetric.

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15. (Original) The staple of claim 13, wherein one of the everting elements moves laterally with respect to the staple body as the staple is bent, such that the direction of closure of the staple is at an angle to the staple body.

16. (Previously Presented) The staple of claim 1, wherein the staple body is outside a lumen of the anastomosed anatomical structures when the everting elements are apposed.

17. (Previously Presented) The staple of claim 1, constructed such that a lumen of the anastomosed anatomical structures is free of exposure to the staple and to cut tissue edges of the anatomical structures.

18. (Original) The staple of claim 1, wherein the staple is formed of a memory metal.

19. (Previously Presented) A surgical staple for use in creation of an everted anastomosis between at least two anatomical structures, the staple comprising means for bending and means for everting connected to and protruding from the means for bending, the means for bending and the means for everting being constructed and arranged so that when the means for bending is bent around cut ends of the anatomical structures, the means for everting forms an apposed relationship and the inner layers of the anatomical structures are held together between the means for everting to form the everted anastomosis; the staple further comprising means for spacing connected to the staple body, the means for spacing being constructed and arranged so that when

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the staple body is bent about a bend thereof and around the cut ends of the anatomical structures, the means for spacing are in an apposed relationship, the cut ends of the anatomical structures are held together between the means for spacing, the means for spacing are disposed closer to the bend than the means for everting are to the bend, and the means for everting are disposed closer to a lumen of the anastomosis than the means for spacing are to the lumen.

20. (Cancelled)

21. (Previously Presented) The staple of claim 19, wherein the means for everting are disposed on opposite ends of the staple, the means for spacing are disposed on opposite ends of the staple, and the staple further comprises means for penetrating that extends from one of the anatomical structures into one other of the anatomical structures.

22. (Previously Presented) A surgical staple constructed to join at least two anatomical structures, the staple comprising:

a first everting platform disposed at a first end of the staple, the first everting platform being centered at the first end of the staple;

a second everting platform disposed at a second end of the staple, the second everting platform being connected at one end thereof to the second end of the staple, the first and second everting platforms being constructed to form an everted anastomosis of the anatomical structures;

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a first spacing element disposed at the first end of the staple, the first spacing element being disposed adjacent the longitudinal axis of the staple;

a second spacing element disposed at the second end of the staple, the second spacing element being disposed along the longitudinal axis of the staple; and

a single penetrating element for penetrating the anatomical structures, the penetrating element being disposed at the first end of the staple along the longitudinal axis of the staple.

23. (Original) The staple of claim 22, wherein the staple is constructed to bend to a closed configuration in which the second everting platform is disposed parallel to the first everting platform and in which the first and second everting platforms are disposed on the same side of the penetrating element.

24. (Original) The staple of claim 23, wherein in the closed configuration the first and second spacing elements are apposed.

25. (Original) The staple of claim 24, wherein in the closed configuration the first and second spacing elements and the penetrating element define an inner radius of the staple; further wherein in the closed configuration the first and second everting platforms define an outer radius of the staple.

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26. (Original) The staple of claim 23, wherein in the closed configuration the staple is bent into a “U” shape to form two legs and a bend, the legs of the staple being offset from each other in two dimensions.

27. (Cancelled)

28. (Cancelled)

29. (Cancelled)

30. (Currently Amended) A device for use in creating an anastomosis of two anatomical structures, the device being constructed to bend to a closed position to create the anastomosis, the anastomosis defining a central lumen, the device comprising:

penetration structure for penetrating and holding both anatomical structures at the anastomosis; and

eversion structure for everting an end of at least one of the anatomical structures, the eversion structure being disposed closer to the lumen of the anastomosis than the penetration structure and the penetration structure being disposed closer to the bend than any portion of the eversion structure is disposed to the bend when the device is in the closed position, the eversion structure being constructed to accommodate the anatomical structures wherein the eversion

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structure forms a general T-shape at one end of the device and forms a general L-shape at another end of the device.

31. (Original) The device of claim 30, wherein the device is constructed from a memory metal such that a crimping tool is unnecessary to create the anastomosis.

32. (Original) The device of claim 30, further comprising spacing structure for providing space within the eversion structure to minimize tissue necrosis in the anatomical structures.

33. (Original) The device of claim 30, wherein the device is a surgical staple, further wherein the penetration structure defines an inner radius of the staple and the eversion structure defines an outer radius of the staple, placement of the inner radius and outer radius causing the staple to be excluded from the lumen of the anastomosis.

34. (Original) The device of claim 30, wherein the device is a surgical staple having a staple body, further wherein the eversion structure comprises two everting platforms protruding from the staple body.

35. (Original) The device of claim 30, wherein the device is an everting surgical staple, the everting surgical staple being in combination with at least one non-everting surgical staple to form the anastomosis.

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36. (Currently Amended) A surgical staple for use in creating an everted anastomosis of at least two anatomical structures, the staple comprising a generally cylindrical staple body constructed for bending and at least two everting elements connected to opposite ends of the staple body, the everting elements being of generally the same length and protruding from the staple body, one of the everting elements being constructed to protrude from the staple body more than another of the everting elements protrudes from the staple body, the staple body and the everting elements being constructed and arranged so that when the staple body is bent around cut ends of the anatomical structures, the everting elements are in an apposed relationship and the inner layers of the anatomical structures are held together between the everting elements to form the everted anastomosis wherein at least two spacing elements are connected to the staple body, the spacing elements being constructed and arranged so that when the staple body is ~~bend~~ bent around the cut ends of the anatomical structures, the spacing elements are in apposed relationship and the cut ends of the anatomical structures are held together between the spacing elements, and a penetrator for penetrating that extends from one of the anatomical structures into another of the anatomical structures.

37. (Cancelled)

38. (Previously Presented) The staple of claim 36, wherein the everting elements are offset from each other transversely with respect to the staple body; further wherein one of the everting

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elements is off-center on the staple body; further wherein one other of the everting elements is centered on the staple body.

39. (Previously Presented) The staple of claim 36, wherein the staple body twists and one of the everting elements moves laterally with respect to the staple body as the staple is bent, such that the direction of closure of the staple is at an angle to the staple body.

40. (Previously Presented) The staple of claim 36, wherein each of the everting elements defines first and second ends, the staple body and everting elements being constructed and arranged so that when the staple body is bent around cut ends of the anatomical structures, the lengths of the everting elements are aligned such that the first ends are aligned with each other and the second ends are aligned with each other.